AUG 01 2002 K021549 page 1 of 4

510(K) Summary
of Safety and Effectiveness

In accordance with the Food and Drug Administration Rule to implement provisions of the Safe Medical Devices Act of 1990 and in conformance with 21 CFR 807, this information serves as a Summary of Safety and Effectiveness for the Contoured Articular Prosthetic (CAP) Femoral Head Resurfacing System.

Submitted By:
STD Manufacturing, Inc.
1063 Turnpike Street
Stoughton, MA 02072
(781) 828-4400

Date:
May 6, 2002

Contact Person:
Steven W. Ek
VP Development

Proprietary Name:
Contoured Articular Prosthetic (CAP)
Femoral Head Resurfacing System

Common Name:
Prosthesis, Hip, Hemi-, Resurfacing, Metallic

Classification Name:
Prosthesis, Hip, Femoral (Hemi-hip), Metallic Resurfacing
Orthopedic
21 CFR § 888.3400
Class II

Product Code:
KXA

Device Description:

The Contoured Articular Prosthetic (CAP) system is intended for resurfacing of the femoral head in patients with post-traumatic degenerative disease or avascular necrosis. The natural acetabulum bearing surface and supportive bone structure should be essentially normal. The device is a single use implant intended to be used with bone cement.

The CAP implant consists of two components, a fixation component and an articular component, that mate together via a taper interlock to provide stable and immobile fixation of the implant and stress bearing contact at the bone/ prosthetic interface.

The fixation component is a modified cancellous screw manufactured of a Ti-6Al-4V ELI alloy per ASTM F136. The screw has a tapering distal tip, a full-length cannulation, and a proximal female taper bore.

The articular component is a dome shaped component manufactured of a Cobalt-Chromium-Molybdenum alloy per ASTM F799 and ASTM F1537. The articular component has a bone contact surface that is coated with a CP Titanium coating and a polished articular bearing surface.

Utilizing the drill guide provided within the CAP instrumentation set, a surgeon is able to define a working axis that is normal to the articular cartilage surface at the site of the defect. After drilling a pilot hole, the fixation component is screwed into place using the trial cap to ensure that the surface of the articular component will be tangent and congruent to the existing cartilage surface when seated. Using the contact probe instrument corresponding to the implant diameter, offset measurements are taken to define the topography of the patients surrounding articular surface by revolving the probe around a centering shaft coaxial to the working axis of the screw. With these offset measurements, the surgeon is able to select the articular component (sized to match femoral head sizes from 40mm to 58mm) that will allow it to seat flush to the surrounding articular surface. Offset increments in .5mm sizes will allow for an optimal fit to the existing articular cartilage.

A reamer, which matches the articular component internal geometry is used to prepare the site for the prosthetic to be implanted. This allows for a precise fit of the implant to the prepared site and minimizes bone resection, so as to provide minimal impact to any future arthroplasty procedure. The articular component is then impacted to seat the taper interlock between the two components.

The prosthetic is intended to provide an effective means for managing pain and disability in the younger patient until a total or joint arthroplasty treatment option becomes more necessary and less likely to create an early-age-revision scenario. The prosthetic may also provide a treatment option for the older patient who may not tolerate the morbidity of a total joint arthroplasty procedure.

Substantial Equivalence Information:

The intended use, materials, and application of the candidate device are substantially equivalent to those of the predicate devices as shown:

Comparison Information for Candidate and Predicate Devices			
Product Name	**Candidate Device:** Contoured Articular Prosthesis (CAP) Femoral Head Resurfacing System	**Predicate Device:** Cormet 2000 Hemi Hip Metallic Resurfacing Prosthesis	**Predicate Device:** Nelson Resurfacing Head
K Number	TBD	K994153	K983452
Product Code	KXA	KXA	KXA
Regulation Number	888.3400	888.3400	888.3400
Intended Use	Resurfacing a portion of the femoral head in patients with post-traumatic degenerative disease or avascular necrosis. The device is a single use implant intended to be used with bone cement.	Resurfacing a portion of the worn femoral head, and so instate function of the hip joint following the degenerative effects of osteo and rheumatoid arthritis, post traumatic disease, and avascular necrosis. Also intended for patients having deformities of the hip that do not lend themselves to conventional total hip replacement such as previously failed femoral osteotomy, previous fracture, or early deformities of the proximal end of the femur.	Resurfacing Prosthesis of the femoral hip joint (Hemi-Hip) for saving the natural femur and providing a new surface on the femoral head for the hip to pivot on. For cemented applications and for single use implantation in: non-inflammatory degenerative joint disease, including osteoarthritis and avascular necrosis, and rheumatoid arthritis.
Indications for Use Statement	Relief of pain and disability, and restoration of hip function within patients who have radiographic evidence of good bone stock in the femoral head and acetabulum, the bearing surface and supportive bone structure of the acetabulum being normal.	Relief of pain and disability, and restoration of hip function within patients who have radiographic evidence of good bone stock in the femoral head and acetabulum, the bearing surface and supportive bone structure of the acetabulum being normal.	Non-inflammatory degenerative joint disease, including osteoarthritis and avascular necrosis and rheumatoid arthritis.
Patient Selection	Patients with pain or loss of function, whose age at the time of treatment suggests that a revision of the prosthetic is possible.	Patients with pain or loss of function, whose age at the time of treatment suggests that a revision of the prosthetic is possible.	Patients with pain or loss of function, whose age at the time of treatment suggest that a revision of the prosthetic is probable.
Material	Cobalt-Chromium-Molybdenum	Cobalt-Chromium-Molybdenum	Cobalt-Chromium-Molybdenum
Designed to Resurface or Replace Articular Surface	Femoral Head Resurfacing Technique	Femoral Head Resurfacing Technique	Femoral Head Resurfacing Technique
Prosthetic Implant site and Bearing Surface	Prosthetic implanted into head of femur, replacing only a small portion of the femoral head. Bearing surface contacts natural acetabulum.	Prosthetic implanted into head of femur, replacing only a small portion of the femoral head. Bearing surface contacts natural acetabulum.	Prosthetic implanted onto head of femur, providing new surface to femoral head. Bearing surface contacts natural acetabulum.

Product D scription	Candidate Device: Contoured Articular Prosthesis (CAP) Femoral Head Resurfacing System	Predicate Device: Cormet 2000 Hemi Hip Metallic Resurfacing Prosthesis	Predicate Device: Nelson Resurfacing Head
K Number	TBD	K994153	K983452
Mechanical Fixation	Fixation screw installed as central post. Prosthesis mates into screw via taper interlock.	Prosthetic press fits into prepared femoral head. Prosthetic has a central smooth post which inserts into pilot in femoral head.	Prosthetic press fits onto prepared femoral head. Prosthetic has a central smooth post which inserts into pilot in femoral head.
Cemented / Non-Cemented	Cemented	Cemented	Cemented
Surface Coating	Yes/ Plasma Spray Ti	Yes/ Unknown	Yes/ Plasma Spray Ti
Site Preparation	Resection of articular surface and bone	Resection of articular surface of femoral head	Resection of articular surface of femoral head

Potential risks associated with this device are the same as with other joint prosthetic devices. These include, but are not limited to:

- Reaction to the bone cement
- Reaction to the implant materials
- Nerve palsy
- Embolus
- Implant loosening/ migration
- Infection
- Delayed wound healing
- Damage to the implants
- Excessive wear
- Hematoma
- Need for Revision
- Incomplete resolution of symptoms

A number of clinical benefits are offered by the device. The device is technically very easy to implant, and offers the surgeon a high degree of precision and flexibility in sizing and fitting the articular component to the existing anatomy. A reduction in bone and articular cartilage resection is also offered over the predicate devices, providing a more physiologically normal joint in terms of load and impact distribution.

Additional materials, manufacturing, and performance data to support the safety and effectiveness of the CAP System are provided within this Premarket Notification.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 0 1 2002

Mr. Steven W. Ek
Vice President, Development
STD Manufacturing
1063 Turnpike Street
Stoughton, Massachusetts 02072

Re: K021549
Trade/Device Name: Contoured Articular Prosthesis (CAP) Femoral Head Resurfacing System
Regulation Number: 21 CFR 888.3400
Regulation Name: Hip Joint Femoral (Hemi-Hip) Metallic Resurfacing Prosthesis
Regulatory Class: Class II
Product Code: KXA
Dated: May 10, 2002
Received: May 13, 2002

Dear Mr. Ek:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Celia M. Witten, Ph.D., M.D.
Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K021549

Device Name: **Femoral Head Resurfacing Prosthesis**

Indications for Use:

Relief of pain and disability, and restoration of hip function within patients who have radiographic evidence of good bone stock in the femoral head and acetabulum, with the bearing surface and supportive bone structure of the acetabulum being normal. The device is a single use implant intended to be used for cemented, hemi-hip, resurfacing applications only.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ (Per 21 CFR 801.109)

Over-The Counter Use No

(Optional Format 1-2-96)

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K021549